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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,195	02/27/2006	Carmit Levita	C&R - 103	1351

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EXAMINER	
MACFARLANE, STACEY NEE	
ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
08/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,195	LEVITA ET AL.	
	Examiner	Art Unit	
	Stacey MacFarlane	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *46-66* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 46 and 48 are objected to as reciting an improper Markush Group. MPEP 803.02 states:

"Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).

Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility."

Applicant is advised that claims 46 and 48 are each improper Markush claims because the plurality of amino acid sequences, nucleic acid sequences, antibodies, kits, vaccines, and transgenic animals recited in these claims lack a common utility that is based upon a shared structural feature lacking from the prior art. Each of these proteins and nucleic acids are independent and distinct chemical compounds lacking either a common structural property which distinguishes them as a group from structurally related compounds of the prior art or which provides them with a common utility which is lacking from those prior art proteins or nucleic acids.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, Claims 46 and 65, in so far as it is drawn to a composition of matter comprising an isolated polypeptide that does not comprise the amino acid sequence recited in SEQ ID NO: 10, wherein said isolated polypeptide is an amino acid sequence comprising that recited in SEQ ID NO:2.

Group 2, Claim 46 and 66, in so far as it is drawn to a composition of matter comprising an isolated polypeptide that does not comprise the amino acid sequence recited in SEQ ID NO: 10, wherein said isolated polypeptide is an amino acid sequence comprising that recited in SEQ ID NO:4.

Group 3, Claim 46, in so far as it is drawn to a composition of matter comprising an isolated polypeptide that does not comprise the amino acid sequence recited in SEQ ID NO: 10, wherein said isolated polypeptide is an amino acid sequence comprising that recited in SEQ ID NO:6.

Group 4, Claim 46, in so far as it is drawn to a composition of matter comprising a purified nucleic acid molecule encoding a polypeptide of SEQ ID NO: 2.

Group 5, Claim 46, in so far as it is drawn to a composition of matter comprising a purified nucleic acid molecule encoding a polypeptide of SEQ ID NO: 4.

Group 6, Claim 46, in so far as it is drawn to a composition of matter comprising a purified nucleic acid molecule encoding a polypeptide of SEQ ID NO: 6.

Group 7, Claim 46, in so far as it is drawn to a composition of matter comprising an antibody that binds specifically to the polypeptide of SEQ ID NO: 2.

Group 8, Claim 46, in so far as it is drawn to a composition of matter comprising an antibody that binds specifically to the polypeptide of SEQ ID NO: 4.

Group 9, Claim 46, in so far as it is drawn to a composition of matter comprising an antibody that binds specifically to the polypeptide of SEQ ID NO: 6.

Group 10, Claim 46, in so far as it is drawn to a composition of matter comprising a compound that that binds to the polypeptide of SEQ ID NO: 2.

Group 11, Claim 46, in so far as it is drawn to a composition of matter comprising a compound that that binds to the polypeptide of SEQ ID NO: 4.

Group 12, Claim 46, in so far as it is drawn to a composition of matter comprising a compound that that binds to the polypeptide of SEQ ID NO: 6.

Group 13, Claim 46, in so far as it is drawn to a transgenic animal that has been transformed to express the polypeptide of SEQ ID NO: 2.

Group 14, Claim 46, in so far as it is drawn to a transgenic animal that has been transformed to express the polypeptide of SEQ ID NO: 4.

Group 15, Claim 46, in so far as it is drawn to a transgenic animal that has been transformed to express the polypeptide of SEQ ID NO: 6.

Group 16, Claims 47-64, in so far as they read upon a method of using the isolated polypeptide is an amino acid sequence comprising that recited in SEQ ID NO:2.

Group 17, Claims 47-64, in so far as they read upon a method of using the isolated polypeptide is an amino acid sequence comprising that recited in SEQ ID NO:4.

Group 18, Claims 47-64, in so far as they read upon a method of using the isolated polypeptide is an amino acid sequence comprising that recited in SEQ ID NO:6.

Group 19, Claims 47-64, in so far as they read upon a method of using a purified nucleic acid molecule encoding a polypeptide of SEQ ID NO: 2.

Group 20, Claims 47-64, in so far as they read upon a method of using a purified nucleic acid molecule encoding a polypeptide of SEQ ID NO: 4.

Group 21, Claims 47-64, in so far as they read upon a method of using a purified nucleic acid molecule encoding a polypeptide of SEQ ID NO: 6.

Group 22, Claims 47-64, in so far as they read upon a method of using an antibody that binds specifically to the polypeptide of SEQ ID NO: 2.

Group 23, Claims 47-64, in so far as they read upon a method of using an antibody that binds specifically to the polypeptide of SEQ ID NO: 4.

Group 24, Claims 47-64, in so far as they read upon a method of using an antibody that binds specifically to the polypeptide of SEQ ID NO: 6.

Group 25, Claims 47-64, in so far as they read upon a method of using a compound that binds to the polypeptide of SEQ ID NO: 2.

Group 26, Claims 47-64, in so far as they read upon a method of using a compound that binds to the polypeptide of SEQ ID NO: 4.

Group 27, Claims 47-64, in so far as they read upon a method of using a compound that binds to the polypeptide of SEQ ID NO: 6.

The inventions listed as Groups 1-27 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the single general inventive concept that permeates the groups is a polypeptide encoded by SEQ ID NO: 2. The expression "special technical feature" is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions makes over the prior art. Whether a particular feature makes a contribution over the prior art, is considered with respect to novelty and inventive step. In the instant application, the polypeptide encoded by SEQ ID NO: 2 does not make a contribution over the prior art. The following reference teaches a polypeptide sequence "comprising an amino acid sequence recited in SEQ ID NO: 2" as required by Claim 46 (Swiss-Prot entry P21741, published May 1, 1991). The prior art recites the common technical feature of the Groups, thus, there is no special technical feature over the prior art and the application lacks Unity of Invention under PCT Rule 13.1.

Species Election

2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Elect one condition for diagnosis from the list of Claim 60.

Elect a condition for treatment from the list of Claim 49.

(Claims 50 and 51) Elect either the method wherein the expression and/or activity of the elected nucleic or polypeptide is lower in a diseased patient, OR the method wherein the expression and/or activity of the elected nucleic or polypeptide is higher in a diseased patient.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Currently, there are no generic claims.

3. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species comprise distinct compositions of matter (i.e. nucleic acid molecules versus polypeptides) that are structurally distinct from one another.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be

treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacey MacFarlane whose telephone number is (571) 270-3057. The examiner can normally be reached on Monday-Thursday 6:30AM-4:00 PM & ALT. Fridays, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

SNM

OLGA N. CHERNYSHEV, PH.D.
PRIMARY EXAMINER